

REMARKS

Claims 1-4, 6, 8-16, 30-32, 34 and 36-82 are pending. Claims 1, 2, 4, 6, 8-16, 30-32, 34, 36-44 and 46-82 are under examination. Claims 6, 34 and 47 have been canceled. Claims 1, 8, 16, 30, 36 and 48 have been amended. New claim 83 has been added. Support for the amendment can be found throughout the specification and the claims as filed. In particular, support for the amendment to the claims to recite that n represents the number of different molecules can be found, for example, on page 51, line 17, to page 52, line 1, which indicates that the methods of the invention can be used to analyze at least two and up to many different molecules. Support for the amendment to recite that the multidimensional space contains n axes, each of the axes relating to the expression level of a molecule of the n molecules, can be found, for example, in Figures 1 and 2 and page 3, line 21, to page 4, line 13, which show exemplary multidimensional analysis of 2 and 3 dimensions, respectively, with each axis relating to the expression level of a molecule. The amendment is further supported on page 71, line 26, to page 72, line 8, which indicates that a similar analysis can be applied in n -dimensional space higher than 2 or 3 dimensions. Claims 8, 36 and 48 have been amended to correct dependency and antecedent basis. Support for new claim 83 can be found in original claim 9, from which claim 83 depends. Accordingly, these amendments and new claim do not raise an issue of new matter and entry thereof is respectfully requested.

Applicants appreciate the time and helpful discussion between Examiner Zhou and supervisory Examiner Marschel and Applicants' representative in the telephone conference of November 8, 2005. Applicants believe that the response addresses the issues discussed in the telephone interview.

As requested, a brief summary of the telephone interview is provided. The claim language was discussed in light of the prior art rejection as well as proposed amendments to the claims. The claims have been amended as discussed in the telephone interview.

Regarding the previously filed amendment, the Office Action has noted that the identifier for claim 32 was indicated to be "Original" even though the claim was marked for amendment. Applicants apologize for this oversight. In the present response, the identifier for claim 32 is "Previously presented" to indicate the previous amendment of claim 32.

Rejection Under 35 U.S.C. § 112, First Paragraph

The rejection of claims 57-64, 66-73 and 75-82 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description and being directed to new matter is respectfully traversed. Applicants maintain that the specification provides sufficient description and guidance for the claimed methods.

The Office Action acknowledges that the specification teaches 2-dimensional and 3-dimensional coordinates as in Figures 1 and 2 but asserts that the specification does not describe a space of more than 3 dimensions. The new claims are thus considered to be directed to new matter.

Applicants respectfully disagree with the assertion that claims 57-64, 66-73 and 75-82 are directed to new matter. The specification teaches that a simplified example of a multidimensional analysis is shown in Figure 1 (page 3, line 21, to page 4, line 3; page 69, line 24, to page 71, line 6). Figure 1 illustrates a multidimensional analysis having 2 dimensions, where each axis relates to the expression level of one molecule of the 2 molecules. The expression level of molecule 1 is plotted against the expression level of molecule 2 for an individual. Thus, each circle in Figure 1 represents a multidimensional coordinate point representative of the expression level of 2 molecules in an individual, shown in 2-dimensional space (page 3, line 21, to page 4, line 3).

The specification further teaches that multidimensional analysis can be performed with additional parameters, for example, in 3-dimensional space, as illustrated in Figure 2 (page 4, lines 4-13; page 71, lines 7-25). In Figure 2, each circle represents a multidimensional coordinate point representative of the expression level of 3 molecules in an individual, shown in 3-dimensional space, where each axis relates to the expression level of one of the 3 molecules in an individual.

The specification goes on to teach that, in addition to 2-dimensional and 3-dimensional analysis, a similar analysis can be applied in n-dimensional space, where n is the number of molecules in a sample of molecules (page 71, line 26, to page 72, line 8). Moreover, the specification teaches that the methods of the invention are advantageous in that multiple parameters are analyzed and the methods can be used to analyze at least two and up to many molecules in a sample and, further, specifically teaches that a sample of molecules can contain 2 or more, 3 or more, 5 or more, 10 or more, etc., including the number of molecules specifically recited in claims

57-64, 66-73, and 75-82 (page 51, line 17, to page 52, line 1). Thus, Applicants respectfully submit that the limitations in these claims are explicitly taught in the specification and are therefore not directed to new matter. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Rejections Under 35 U.S.C. § 112, Second Paragraph

The rejection of claims 1, 2, 4, 6, 8-16, 30-32, 34, 36-44 and 46-82 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite is respectfully traversed. Applicants respectfully submit that the claims are clear and definite.

The Office Action indicates that independent claims 1, 16 and 30 are unclear as to whether, the number of molecules being analyzed refers to the number of different molecules being analyzed or the absolute number of molecules of a particular molecule. "It is unclear what is meant by 'the number of molecules being analyzed.' It could mean, as it appears literally, how many molecules, same or not, being analyzed. Or it could mean how many different molecules being analyzed" (Office Action page 4, first paragraph). Applicants respectfully submit that it is clear that the number of molecules refers to the number of different molecules in that the claims refer to the expression levels of the n molecules, for example, as recited in step (b). Nevertheless, to further prosecution, claims 1, 16 and 30 have been amended to recite that n represents the number of different types of molecules being analyzed. In the example provided in the Office Action, the question is raised as to whether the number of molecules refers to the absolute number of all molecules being analyzed (for example, 100 molecules of A and 200 molecules of B for a total of 300 molecules) or the number of different types of molecules, that is, 2 molecules designated A and B. The claims, as amended, specifically recite "the number of different molecules," which in the example referred to in the Office Action would be two different molecules, A and B. Accordingly, Applicants respectfully submit that these claims are clear and definite and respectfully request that this rejection be withdrawn.

The Office Action indicates that claims 6, 34 and 47 are unclear due to lack of antecedent basis for the phrase "said sample." Applicants respectfully submit that this rejection has been rendered moot by the cancellation of these claims and request that this rejection be withdrawn.

The Office Action further indicates that claims 30-32 are unclear for the phrase "substantially similar response." Applicants respectfully submit that the phrase "substantially similar response" is clear and definite. The specification teaches that a substantially similar response to a drug can refer to a substantially similar expression profile as indicated by a corresponding multidimensional coordinate point residing within a drug response-associated reference expression region such that individuals having expression of molecules within the reference expression region have a substantially similar drug response (page 43, lines 15-21). The specification additionally teaches that a substantially similar response to a drug can also refer to individuals having overt manifestations or indications associated with a drug response that can be objectively determined by the skilled artisan physician, for example, based on signs of a disease or a test result or based on symptoms described by the patient (page 43, lines 22-30). Thus, the specification teaches that a substantially similar response can be readily determined by the skilled artisan physician by making an assessment as to whether a drug response is substantially similar to another or can be determined by the statistical methods as taught in the specification. Therefore, Applicants respectfully submit that the meaning of the phrase "substantially similar response to a drug" is clear and definite. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Rejections Under 35 U.S.C. § 102

The rejection of claims 1, 2, 4, 6, 8-16, 30-32, 34, 36-44 and 46-55 under 35 U.S.C. § 102(e) as allegedly anticipated by Friend et al., U.S. Patent No. 6, 218,122, is respectfully traversed. Applicants respectfully maintain, for the reasons of record and as discussed in the telephone interview conducted November 8, 2005, that the claimed methods are novel over Friend et al.

As discussed in the previous responses filed May 17, 2005, and August 24, 2004, Applicants respectfully maintain that Friend et al. does not teach the claimed methods using multidimensional analysis. As discussed in the Rule 132 Declaration filed with the response mailed August 24, 2004, Friend et al. describes using unidimensional analysis. In the telephone interview conducted November 8, 2005, the proposed amendment in the present response was discussed, in particular the recitation of the description of the axes of multidimensional space recited in the claims. Claims 1, 16 and 30 have been amended to recite that the multidimensional space contains n axes, where each

of the axes relates to the expression level of a molecule of the n molecules. For example, if n is 2 molecules, the multidimensional space contains 2 axes, each of which relates to the expression level of one of the 2 molecules, as illustrated in Figure 1. If n is 3 molecules, the multidimensional space contains 3 axes, each of which relates to the expression level of one of the 3 molecules, as illustrated in Figure 2. If n is 4 molecules, the multidimensional space contains 4 axes, each of which relates to the expression level of one of the 4 molecules, and so forth for a larger number of molecules.

As discussed in the telephone interview, Friend et al. does not teach multidimensional analysis and further does not teach creating a multidimensional space of n dimensions, wherein n represents the number of different molecules being analyzed in a specimen from each individual in a population of individuals administered a drug and wherein the multidimensional space contains n axes, each of the axes relating to the expression level of a molecule of the n molecules. Absent such a teaching, Friend et al. cannot anticipate the claims.

Applicants respectfully submit that the claimed methods are novel over Friend et al. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Objections to the Claims

The objection to claims 1, 2, 4, 6, 8-16, 30-32, 34, 36-44 and 46-82 due to informalities is respectfully traversed. As requested by the Examiner, claims 1, 16 and 30 have been amended to correct a typographical error. Accordingly, Applicants respectfully request that the objection to the claims be withdrawn.

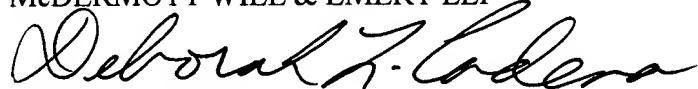
In light of the amendments and remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. The Examiner is invited to call the undersigned agent if there are any questions.

09/919,360

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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